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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,781	08/28/2006	Rolf Muller	0112843-001 - 91905 US	5896
24573	7590	05/14/2010		
K&L Gates LLP			EXAMINER	
P.O. Box 1135			ANDERSON, JERRY W	
CHICAGO, IL 60690				
		ART UNIT	PAPER NUMBER	
		1781		
		MAIL DATE	DELIVERY MODE	
		05/14/2010	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/583,781

**Applicant(s)**

MULLER ET AL.

**Examiner**

JERRY W. ANDERSON

**Art Unit**

1781

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 1/19/2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 3, 5, 6 and 8-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 5, 6, and 8-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/GS/US)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Examiner acknowledges the receipt of the Applicant's Amendment, mailed 1/19/2010. Claims 1 and 8 amended, claims 1, 3, 5-6, and 8-17 pending. The amendments to the specification, amending typographical errors, is entered.

### **Specification**

The amendments to the specification filed 1/19/2010 has t been entered. Said amendments fix obvious errors in paragraphs 38 and 40 of pgpub 2007/0134392.

### **Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, the claim was amended to include the term "a polymerization level < 100 relative to the starch product." The claim does not define the term "polymerization level" and the specification does not provide a definition of the term. The specification states that it is advantageous to use a short chain amylose with a polymerization level of less than 300, 100 preferably 70 and most preferably less than 50. (¶19, specification) This is not an explicit

and clear definition, but merely an exemplification of a desired result. The term "polymerization level" is not defined in the claim nor in the specification.

### **Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- Determining the scope and contents of the prior art.
- Ascertaining the differences between the prior art and the claims at issue.
- Resolving the level of ordinary skill in the pertinent art.
- Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3, 5-6, and 8-17, are rejected under 35 U.S.C. 103(a) as being unpatentable over Shi Y-C., et al., (6,890,571) in view of Haralampu, S.G., et al. (5, 849,090)

Regarding Claim 1, 8, 11, 14, and 15, the Applicant claims a slow digestible starch product, with a swellable network, crystallites and an initial hydrolysis rate of  $<300\%/h$ . Shi teaches a resistant, gelatinized, crystallized starch, (lines 6-9 col. 3, lines 34-35, 46-48 col. 4, '571) a starch that is resistant to digestion in the small intestine, and passes into the large intestine, ( line 13-15 col. 1, '571 ) The applicant determines the hydrolysis rate by measuring the amount of undigested starch at intervals of .5, 1, 2, 3, 4, 5, and 6 hours and calculating the digested portion of the starch. This data is shown in Table 1 and plotted in Figures 1-5, (applicant's specification) Applicant states that Shi's data is comparable to amylase treated cornstarch, with a  $H_o$  of  $200\%/hr$ ,  $H_c$  of  $200\%/hr$  and a  $T_c$  of 0.25 hours. (§ 46, Table 1, Applicant) However, comparison of the data in Shi's Table 1, samples 1B and 1D, the % digested values at 20 min and 120 minutes, which are approximately 24 % and 49 %, (table 1, '571) respectively with the applicant's data yields different results. Said data when plotted on the applicants graph in Fig. 3, are similar in performance, if not slightly better than the results of samples WS 72-2 through 4, which have  $H_o$  ( $\%/h$ ) of 70-90,  $H_c$  ( $\%/h$ ) of 20-22 and  $T_c$  (h) of 2.5. When compared with Fig. 4, the values of Shi's samples 1B and 1D appear to be almost identical to the data points of Sample WS-55-3, which has a  $H_o$  of 54,  $H_c$  of 16 and a  $T_c$  of 2.5 hours. One of ordinary skill in the art would find it obvious that Shi's samples 1B and 1D, exhibiting similar values when compared to the aforesaid applicant data would have similar results to the  $H_o$ ,  $H_c$  and  $T_c$  values of the applicant's samples.

Therefore, interpolation of the applicant's data would yield for Shi's samples 1B and 1D an estimated value of about,  $H_o$ : 54-90 (%/h),  $H_c$ : 14-22 (%/h) and  $T_c$ : 2.5 hours. A process of manufacturing a slowly digestible starch product prepared by enzymatically debranching low amylose starches and allow the resultant linear short chains to crystallize to a highly crystalline form, (lines 20-25, col. 2, '571) with an initial hydrolysis rate of less than 300 %/h. (pg 46, Table 1, Applicant) and a  $T_c$  of at least 0.5 hours. Shi defines short chain amylose as linear polymer containing from about 5 to 65 anhydroglucose units linked by alpha-1,4-D-glucoside bonds. (lines 65-67, col. 1, '571) One of ordinary skill in the art would find it obvious that this definition of short chain amylose complies with the applicant's degree of polymerization of less than 100.

However, Shi lacks a starch product has a 2-70 % w/w short chain amylose, the use of a starch containing greater than 20 % amylose content, and the use of extrusion.

As to the 2-70 % short chain amylose content of the starch product, Shi teaches the making of a slowly digestible starch product by enzymatically debranching low amylose starches and allowing the resultant linear short chains to crystallize to a highly crystalline form, (lines 20-25, col. 2, '571) wherein enzyme reaction is continued until a slowly digestible starch is achieved, (lines 32-34, col. 3, '571) and the amount of hydrolysis may be monitored, (lines 38, col. 3, '571) optionally the enzyme may be deactivated, (line 51, col. 3, '571) the debranched starch is further characterized by the dextrose equivalent (D.E.), and

a lower dextrose equivalent may be achieved by altering the processing conditions, (lines 57-61, col. 4, '571) DE is inversely related to molecular weight, the DE of anhydrous D-glucose is defined as 100 and the DE of unhydrolyzed starch is virtually zero. (lines 65-67, col. 4, '571) Therefore if one desired to produce a lower percentage of short chain amylose in the product, one could stop the reaction prior all of the completion of amylopectin debranching by the enzyme. For instance, Shi monitored the reactions as follows: the debranching reaction was stopped when the DE reached 6.0, (lines 61-63, col. 7, '571) the reaction proceeded for 8 hours, the debranched starch had a DE of 7.0, (lines 9-16, col. 8, '571) the debranching reaction was stopped when the DE reached 5.3, (lines 23-24, col. 8, '571) after 5 hours the pH, reaction stopped, DE of 6.7. (lines 55-61, col. 8, '571)

One of ordinary skill in the art would find it obvious that the amount of short chain amylose in the starch product could be determined by the operator. Therefore the amount of short chain amylose falls within the province of an ordinary worker in the field, and thus the amount of short chain amylose produced in the reaction carries little or no patentable weight.

Haralampu teaches the use of starches containing at least 30 % amylose, (lines 28-31, col. 3, '090) and the use of heating equipment such as jacketed reactor, heat exchanger, extruder, or direct steam injection. (lines 8-17, col. 4, '090)

Shi and Haralampu are analogous art in that both are concerned with the modification of starches to form a slowly digestible starch.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the methods of Shi by the use of starches containing more than 30 % amylose starches, (lines 28-31, col. 3, '090), to produce physiological benefits of fiber, such as increased fecal bulk, and increased excretion of butyrate and acetate in the colon. (lines 25-28 col. 1, '090).

Regarding Claim 3, Shi and Haralampu disclose the claimed invention, as discussed above, including Shi in Table 1 lists values of SDS slowly digestible starch of 22-26 %, and that all samples contained more than 20 % said slowly digestible starch. (line 44 col. 8 Table 1, '571)

Regarding Claim 5, Shi and Haralampu disclose the claimed invention, as discussed above, including the DSC melting point of at least 70 deg. C. (lines 50-53 col. 4 '571)

Regarding Claims 6 and 10, Shi and Haralampu disclose the claimed invention, as discussed above, including in Example 3 a food product (crackers) made using 39 % resistant starch and the results thereof in Table 3. (lines 20-45 col.9, Table 3 '571)

Regarding Claim 7, Shi and Haralampu disclose the claimed invention, as discussed above, including that the starch is greater than 90 % debranched, (lines 45-50 '571), is highly crystalline, (line 46 col. 4 '571) and that further steps to purify the solution may be used if necessary. (lines 23-33 col. 4 '571)



Regarding claim 9, Shi and Haralampu disclose the claimed invention, as discussed above, including the use of additives to change the functional properties of the resistant starch. (lines 33-43 col. 2, lines 5-19 col. 6 '090)

Regarding claim 12 and 13, Shi and Haralampu disclose the claimed invention, as discussed above, including foods can be formulated with the granular resistant starch in extruded foods such as extruded snacks and cereals. (lines 53-64, col. 2, '090)

Regarding Claim 16, Shi and Haralampu disclose, as discussed above, a process of manufacturing a slowly digestible starch product prepared by enzymatically debranching low amylose starches and allow the resultant linear short chains to crystallize to a highly crystalline form, (lines 20-25, col. 2, '571) with an initial hydrolysis rate of less than 300 %/h. (pg 46, Table 1, Applicant) and a Tc of a least 0.5 hours.

Regarding claim 17, Shi and Haralampu disclose the claimed invention, as discussed above, but lacks the use of a tablet. Haralampu discloses granular resistant starch which can be used as a dietary fiber supplement and as a tableting aid, (lines 20-27, col. 6, '090) One of ordinary skill in the art would find it obvious that using the granular starch product as a tableting aid would result in the formation of tablets containing said starch product.

#### **Response to Amendment**

The applicant submitted an amendment to the specification to fix obvious typographical errors. The amendment is hereby entered.

The applicant amended claims 1 and 8 to include the term "wherein the starch product has a 2-70 % w/w short-chain amylose with a polymerization level < 100 relative to the starch product".

Shi states the short chain amylose refers to a linear polymer containing from about 5 to 65 anhydroglucose units linked by alpha-1,4-D-glucoside bonds. (lines 65-67, col. 1, '571) Which to one of ordinary skill in the art would fall within the polymerization < 100 limitation.

The amount of short chain amylose produced by the reaction can be monitored and controlled by the person doing the process, and thus falls within purview of a worker in the art, and thus carries little or no patentable weight.

#### **Response to Arguments**

Applicant's arguments filed 1/19/2010 have been fully considered but they are not persuasive.

The applicant states that the prior art does not teach 2-70 % short chain amylose in the starch product. As detailed above, examiner submits that Shi teaches that the debranching reaction is monitored and the reaction can be stopped as the operator desires. Thus the amount of short chain amylose molecules can be set to any particular value under the operator's control. Thus the amount of short chain amylose being under the control of the operator, carries little or no patentable weight.

Applicant states that Haralampu is teaching away from the instant application by maintaining the granular structure of the starch, throughout the

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debranching reaction. (¶ 3, pg 8, applicant's remarks) However, Haralampu produces a resistant starch, which has similar physical properties to Shi and the instant application: DSC at least 90°C, (line 52, col. 4, '571) DSC 95°C to 145°C. (line 48, col. 8, '090) DSC >70°C. (claim 5, instant application)

Thus the Examiner submits that the granular starch product of Haralampu does not constitute teaching away, in that the product produced exhibits similar characteristics and performs similarly to the product of the instant invention.

### **Conclusion**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY W. ANDERSON whose telephone number is (571)270-3734. The examiner can normally be reached on 7 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. SAYALA/  
Primary Examiner, Art Unit 1781

Jwa